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| <p>(54) Title: ANTERIOR AND INFERIOR SEGMENT CARDIAC RESTORATION APPARATUS AND METHOD</p>  |           |   |
| <p>(57) Abstract</p>   |           |   |
| <p>The symptoms of congenital heart failure are addressed in this surgical procedure for mounting a patch in the ventricle of the heart to reduce ventricular volume. Placement of the patch is facilitated by palpating a beating heart to identify akinetic, although normal appearing, tissue. An apical patch having an oval configuration facilitates return of the heart to a normal apical shape which enhances muscle fiber efficiency and a normal writhing pumping action. An inferior patch having a triangular configuration can also be used. The patches include a semi-rigid ring, and a circumferential rim to address bleeding. Patch placement is further enhanced by creating a Fontan-type neck and use of pledged sutures. Intraoperative vascularization and valve replacement is easily accommodated. Increased injection fraction, reduced muscle stress, improved myocardial protection, and ease of accurate patch placement are all achieved with this procedure.</p> |           |   |

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ANTERIOR AND INFERIOR SEGMENT CARDIAC RESTORATION APPARATUS  
AND METHOD

5                                   Background of the Invention

Field of the Invention

10           This invention relates generally to surgical methods  
and apparatus for addressing ischemic cardiomyopathy, and  
more specifically to methods and apparatus for restoring the  
architecture and normal function of a mammalian heart.

15           Discussion of the Prior Art

          The function of a heart in an animal is primarily to  
deliver life-supporting oxygenated blood to tissue  
throughout the body. This function is accomplished in four  
stages, each relating to a particular chamber of the heart.  
20           Initially deoxygenated blood is received in the right  
auricle of the heart. This deoxygenated blood is pumped by  
the right ventricle of the heart to the lungs where the  
blood is oxygenated. The oxygenated blood is initially  
25           received in the left auricle of the heart and ultimately  
pumped by the left ventricle of the heart throughout the  
body. It can be seen that the left ventricular chamber of  
the heart is of particular importance in this process as it  
30           is relied upon to pump the oxygenated blood initially  
through a mitral valve into and ultimately throughout the  
entire vascular system.

          A certain percent age of the blood in the left  
ventricle is pumped during each stroke of the heart. This

pumped percentage, commonly referred to as the ejection fraction, is normally about sixty percent. It can be seen that in a heart having a left ventricular volume such as seventy milliliters, an ejection fraction of sixty percent would deliver approximately 42 milliliters of blood into the aorta. A heart with reduced left ventricular volume might have an ejection fraction of only 40% and provide a stroke volume of only 28 millimeters.

Realizing that the heart is part of the body tissue, and the heart muscle also requires oxygenated blood, it can be appreciated that the normal function of the heart is greatly upset by clotting or closure of the coronary arteries. When the coronary arteries are blocked, an associate portion of the heart muscle becomes oxygen-starved and begins to die. This is clinically referred to as a heart attack. Ischemic cardiomyopathy typically occurs as the rest of the heart dilates in an attempt to maintain the heart's output to the body.

As the ischemic area loses its contraction, the area of dilatation is restricted to the remaining muscle. The three regions of typical infraction include, 1) the anterior wall septum and anterolateral wall which are supplied by the anterior descending coronary artery; 2) the septum and inferior wall supplied by the left anterior artery and the right coronary artery which narrows due to the heart's elliptical shape; and 3) the lateral wall supplied by the circumflex artery which perfuses the lateral wall including the papillary muscle attachments to the ventricular wall.

As the ischemic cardiomyopathy progresses, the various structures of the heart are progressively involved including the sternum, the apex and the anterolateral wall of the left

ventricle. Within a particular wall, the blood starvation begins at the inside of the wall and progresses to the outside of the wall. It can be seen that addressing ischemic cardiomyopathy shortly after the heart attack can limit the detrimental effects to certain elements of the heart structure, as well as the inner most thicknesses of the walls defining those structures.

As a heart muscle is denied blood nourishment support, its ability to participate, let alone aid, in the cardiac pumping function, is greatly diminished and typically nil. Such muscle is commonly referred to as akinetic, meaning it does not move. In some cases the wall will form elastic scar tissue which tends to balloon in response to the pumping action. This muscle tissue is not only akinetic, in that it does not contribute to the pumping function, but it is in fact dyskinetic, in that it detracts from the pumping function.

The akinetic tissue will, in addition to not contracting, cause cardiac enlargement due to dilatation or loss of its contractile capacity. The dilatation will widen, and thereby change the fiber orientation of the remaining muscle in the left ventricle. This will make the ventricle spherical, and change it from the normal elliptical form which optimizes contraction.

The shape of the ventricle is normally elliptical or conical with an apex that allows a 60 degree fiber orientation of the muscle. This orientation ensures efficient development of intramuscular torsion to facilitate the pumping of blood. Compression of the left ventricular cavity occurs by torsional defamation which thickens the left ventricular wall. This increases progressively from

the mid-ventricular wall to the apex. As a result, maintenance of the apical anchor is a central theme of cardiac contraction.

Perhaps the most notable symptom of ischemic cardiomyopathy is the reduction in the ejection fraction which may diminish, for example, from a normal sixty percent to only twenty percent. This results clinically in fatigue, and inability to do stressful activities, that require an increase in output of blood from the heart. The normal response of the heart to a reduction in ejection fraction is to increase the size of the ventricle so that the reduced percentage continues to deliver the same amount of oxygenated blood to the body. By way of example, the volume of the left ventricle may double in size. Furthermore, a dilated heart will tend to change its architecture from the normal conical or apical shape, to a generally spherical shape. The output of blood at rest is kept normal, but the capacity to increase output of blood during stress (i.e., exercise, walking) is reduced. Of course, this change in architecture has a dramatic effect on wall thickness, radius, and stress on the heart wall. In particular, it will be noted that absent the normal conical shape, the twisting motion at the apex, which can account for as much as one half of the pumping action, is lost. As a consequence, the more spherical architecture must rely almost totally on the lateral squeezing action to pump blood. This lateral squeezing action is inefficient and very different from the more efficient twisting action of the heart. The change in architecture of the heart will also typically change the structure and ability of the

mitral valve to perform its function in the pumping process. Valvular insufficiency can also occur due to dilatation.

5 A major determinant of both cardiac oxygen requirement and efficiency is based upon a formula where stress or pressure is multiplied by the radius and divided by twice the thickness of the cardiac wall. Increasing stress reduces contractility or rejecting capacity, and raises energy requirements in the remaining contracting muscle. As the shape changes from elliptical to spherical, wall stress increases thereby demanding higher energy from the remaining cardiac muscle. This dilation, which occurs anteriorly, effects the septum, apex and anterolateral wall. Thus, the normally oval apex becomes more spherical due to 1) a loss of infarcted muscle, and 2) dilation of the remaining contracting muscle.

20 With inferior coronary artery involvement, the inferior wall, septum, and apex are affected. These elements form, naturally a myocardial triangle, with a base adjacent to the mitral valve, and the septum and free lateral walls forming the planes going to the cardiac apex. As the triangle becomes widened, due to loss of contracting muscle after infraction, the same form of ventricular dilatation occurs. However, instead of making the oval ventricle into a sphere in the anterior segment, with subsequent enlargement (dilatation) of the non-infarcted remaining contracting muscle, there is an increase in the triangle inferiorly. As a result, there is an increase in both the transverse diameter as well as the longitudinal dimension. Thus, inferior coronary involvement results in dilatation of the entire inferior segment.

Although the dilated heart may be capable of sustaining life, it is significantly stressed and rapidly approaches a stage where it can no longer pump blood effectively. In this stage, commonly referred to as congestive heart failure, the heart becomes distended and is generally  
5 incapable of pumping blood returning from the lungs. This further results in lung congestive and fatigue. Congestive heart failure is a major cause of death and disability in the United States where approximately 400,000 cases occur  
10 annually.

Following coronary occlusion, successful acute reperfusion by thrombolysis, (clot dissolution) percutaneous angioplasty, or urgent surgery can decrease early mortality  
15 by reducing arrhythmias and cardiogenic shock. It is also known that addressing ischemic cardiomyopathy in the acute phase, for example with reperfusion, may salvage the epicardial surface. Although the myocardium may be rendered akinetic, at least it is not dyskinetic. Post-infarction  
20 surgical revascularization can be directed at remote viable muscle to reduce ischemia. However, it does not address the anatomical consequences of the akinetic region of the heart that is scarred. Despite these techniques for monitoring  
25 ischemia, cardiac dilation and subsequent heart failure continue to occur in approximately fifty percent of post-infarction patients discharged from the hospital.

The distribution of heart failure is more common with occlusion of the left anterior descending coronary artery  
30 (LAD) due to its perfusion of the apex. But, this can also occur with inferior infarction, especially if there is inadequate blood supply to the apex due to 1) prior damage to the left anterior descending artery, or 2) inadequate



blood supply due to stenosis or poor function. In general, the distribution of ischemia is 45% anterior, 40% inferior, and 15% circumflex. However, the incidence of congestive heart failure is more common in the anterior infarction.

5 Various surgical approaches have been taken primarily to reduce the ventricular volume. This is also intended to increase the ejection fraction of the heart. In accordance with one procedure, viable muscle is removed from the heart in an attempt to merely reduce its volume. This procedure, 10 which is typically accomplished on a beating heart, has been used for hearts that have not experienced coronary disease, but nevertheless, have dilated due to leaking heart valves. Other attempts have been made to remove the scarred portion of the heart and to close the resulting incision. This has 15 also had the effect of reducing the ventricular volume.

In a further procedure, a round, circular patch has been proposed for placement typically in the lateral ventricular wall. Unfortunately, providing the patch with a 20 circular shape has allowed the dilated heart to remain somewhat enlarged with a thin and over-stressed wall section. The exact placement of the patch has been visually determined using only a visual indication where the typically white scar tissue meets the typically red normal 25 tissue. Location of the patch has been facilitated in a further procedure where a continuous suture has been placed around the ventricular wall to define a neck for receiving the patch. The neck has been formed in the white scar 30 tissue rather than the soft viable muscle. This procedure has relied on cardioplegia methods to stop the beating of the heart and to aid in suture placement.

In the past, the patch has been provided with a fixed or semi-rigid wall which has prevented the muscle from becoming reduced to an apical anchor which facilitates the twisting motion. The patches have had a fixed planar configuration which have prevented the lateral muscle from coapting to form an apex.

These surgical procedures have been met with some success as the ejection fraction has been increased, for example, from twenty-four percent to forty-two percent. However, despite this level of success, little attention has been paid to myocardial protection, the potential for monitoring the writhing action associated with apical structure, or the preferred structure for the patch. Failure to protect the heart during restoration of the segment has increased hospital mortality, morbidity, and irreversibly damaged some normal muscle needed to maintain the heart's output.

#### Summary of the Invention

The procedure of the present invention is preferably performed on a beating heart. This is believed to greatly improve the myocardial protection during the restoration process. The procedure further benefits from the beating of the heart by providing a palpable indication of preferred patch placement. As opposed to prior procedures, the primary intent is to exclude, not only the budging dyskinetic segments, but also the non-contracting akinetic segments of the heart which do not contribute to the pumping action. As a result, akinetic segments, despite a normal visual appearance, can be included for exclusion in this

procedure. The process may include an endoventricular Fontan suture, but the stitch will typically be placed in normal tissue with palpable guidance rather than in scar tissue and only a visual determination.

5 A non-circular, anatomically-shaped, typically oval patch is proposed and may be formed of a sheet material such as mammalian fixed pericardium. The patch may include a continuous ring which separates the body of the material from a hemostatic rim or flange which facilitates bleeding control. The patch is fixed to the Fontan neck preferably using pledgeted, interrupted sutures to secure patch placement and avoid distortion. Closure of the excluded ventricle over the hemostatic patch avoids dead space and provides security against patch leaks and resulting expansion.

For anterior infarction, the Fontan suture will change the spherical circular muscle evident by ventricular opening, to an oval configuration which conforms more precisely to the elliptical or gothic ventricular configuration.

For inferior infarction, the endoventricular suture is placed to reform the triangle (i.e., septum, apex, inferior wall) that becomes enlarged by the noncontractile muscle after infarction. This muscle can either appear normal, be scarred trabecularly, or scarred completely to diverge from the normal triangular smaller size configuration. The intent is to "retriangulate" the inferior wall to its more normal configuration.

The restoration of an anatomically shaped apex with an oval patch may include the conical configuration of the patch to ensure progressive re-creation of the cone by the

improving muscle. For this reason, the ring (attached to the more normal remaining muscle but not the contracting muscle) should be completely pliable (not rigid or semi-rigid) to allow reformation of the cone by contracting muscle. As cardiac output improves with ventricular volume reduction and wall motion, contractility increases during healing. A semi-rigid cone or apical patch can fix this transverse diameter to prevent coaptation.

The use of a conical apical patch may avoid closure of the muscle of the excluded area over the patch to thereby allow the normal re-configuration to occur. For this reason, it may be desirable to make the rim of the patch (the border that is not connected to the interventricular chain) to be relatively wide. In this case, a 1-2 centimeter size will typically allow the material surface (i.e., pericardium fascia or other soft element) to be coapted to remaining muscle for hemostatic purposes. Thus, the closure of the muscle over the patch can be avoided without limiting restoration of the apical configuration if bleeding occurs beneath the closed muscle.

These and other features and advantages of the invention will become more apparent with a description of preferred embodiments and reference to the associated drawings.

#### Description of the Drawings

Fig. 1 is a perspective view of the abdominal cavity of a human body showing the heart in cross section;

Fig. 2 is a front plan view of the heart showing coronary arteries which feed the septum, apex and lateral wall of the myocardium;

5 Fig. 3 is a axial cross section view of the ventricular portions of the heart illustrating a dilated, generally spherical left ventricle;

Fig. 4 is an anterior elevation view of the heart with an incision into the left ventricle through dyskinetic scar tissue;

10 Fig. 5 is an anterior elevation view similar to Fig. 4 where the incision is made in marbled akinetic tissue;

15 Fig. 6 is an anterior elevation view similar to Fig. 5 illustrating the incision made in normal-looking akinetic tissue;

Fig. 7 is an axial cross section view of the left ventricle showing the surgeon's hand palpating the myocardium to define an imaginary circumferential line of separation between viable and akinetic tissue;

20 Fig. 8 is an axial cross section view similar to Fig. 7 illustrating the palpating heart and a preferred zone of placement for a patch associated with the present invention;

25 Fig. 9 is an anterior elevation view similar to Fig. 4 and illustrating placement of a Fontan stitch in the ventricular wall;

Fig. 10 is an axial cross section view taken along lines 10-10 of Fig. 9 and illustrating a Fontan neck created by the Fontan stitch;

30 Fig. 11 is a side elevation view of the opening illustrated in Fig. 9 with the Fontan suture tightened to facilitate the natural oval formation of the opening;

Fig. 12A is a plan view of sheet material included in one embodiment of the patch associated with the present invention;

5 Fig. 12B is a cross section view taken along lines 12B-12B of Fig. 12A and illustrating the sheet material in a concave configuration;

Fig. 13 is a top plan view of a ring associated with the patch of the present invention;

10 Fig. 14 is a circumferential cross section taken along lines 14-14 of Fig. 13;

Fig. 15 is a top plan view showing the sheet material and ring combined to form one embodiment of the patch of the present invention;

15 Fig. 16 is a cross section view of the patch taken along lines 16-16 of Fig. 15;

Fig. 17 is a cross section view similar to Fig. 12B and illustrating the sheet material in a convex configuration;

20 Fig. 18 is a cross section view similar to Fig. 16 and illustrating the ring disposed on a concave surface of the sheet material;

Fig. 19 is a cross section view similar to Fig. 18 and illustrating the ring sandwiched between two pieces of the sheet material;

25 Fig. 20 is a cross section view similar to Fig. 19 and illustrating the ring sandwiched between two pieces of material, but having only a single layer in the center of the patch;

30 Fig. 21 is an anterior elevation view similar to Fig. 11 and illustrating the placement of pledgeted, interrupted sutures engaging the patch in a remote location;

Fig. 22A is an axial cross section view of the left ventricle illustrating the patch being moved along the interrupted sutures from the remote location to the Fontan neck;

5 Fig. 22B is a perspective view similar to Fig. 21 and illustrating an alternative method for placement of interrupted sutures;

Fig. 23 is an axial cross section view similar to Fig. 22 and illustrating the patch in its final disposition against the Fontan neck, and further illustrating use of the hemostatic rim to control bleeding;

10 Fig. 24 is an axial cross section view of the ventricular portion of the heart, with the patch mounted in place, the ventricle wall restored to its apical configuration, and the lateral ventricular wall closed in overlapping relationship with the septum wall next to the patch;

20 Fig. 25 illustrates a front elevation view of the heart after it has been lifted from the chest cavity and its apex has been rotated backwardly about its base to expose the inferior wall of the heart;

Fig. 26 is a front elevation view similar to Fig. 25 and illustrating an incising step in a method for patching the inferior wall of the heart;

Fig. 27 is a front elevation view similar to Fig. 26 and illustrating the preferred placement of basting sutures to retriangulate the inferior wall of the heart;

30 Fig. 28 is a front perspective view of a preferred embodiment of an inferior patch being sutured to the heart of Fig. 27;

Fig. 29 is a front elevation view similar to Fig. 28 and illustrating final placement of the patch with a circumferential rim extending outwardly of the ventricle along the inner surface of the inferior wall; and

5 Fig. 30 is a front elevation view similar to Fig. 29 and illustrating final suturing of the circumferential rim to the inner surface of the inferior wall.

Description of Preferred Embodiments and  
10 Best Mode of the Invention

Abdominal portions of the human body are illustrated in Figure 1 and designated by the reference numeral 10. The body 10 is merely representative of any mammalian body  
15 having a heart 12 which pumps blood containing nutrients and oxygen, to vitalize tissue in all areas of the body 10. Other organs of particular importance to this blood circulation process include the lungs 14 and 16, and the  
20 vasculature of the body 10 including arteries which carry blood away from the heart 12 and veins which return blood to the heart 12.

The heart 12 typically includes four chambers, a right  
25 auricle 18, a right ventricle 21, a left auricle 23 and a left ventricle 25. In general, the auricles 18 and 23 are receiving chambers while the ventricles 21 and 25 are pumping chambers. Each of these chambers 18-25 is associated with a respective function of the heart 12. For  
30 example, it is the purpose of the right auricle 18 to receive the deoxygenated blood returning in the veins of the body 10, such as the femoral vein 27. From the right auricle 18, the deoxygenated blood passes into the right



ventricle 21 from which it is pumped through a pulmonary artery 30 to the lungs 14 and 16.

Within the lungs 14 and 16, the deoxygenated blood is reoxygenated and returned to the left auricle 23 of the heart 12 through a pulmonary vein 32. From this chamber,  
5 the oxygenated blood passes through a mitral valve 34 into the left ventricle 25. With each beat of the heart 12, the left ventricle 25 contracts pumping the oxygenated blood into the arteries of the body, such as the femoral artery  
10 36.

The shape of the normal heart 12 is of particular interest as it dramatically affects the way that the blood is pumped. It will be noted, for example, that the left  
15 ventricle 25, which is the primary pumping chamber, is somewhat elliptical, conical or apical in shape in that it is longer than it is wide and descends from a base 35 with a decreasing cross-sectional circumference, to a point or apex 37. The left ventricle 25 is further defined by a lateral  
20 ventricle wall 38, and a septum 41 which extends, between the atrium 18, 23, and between the ventricles 21, 25. The mitral valve 34 is situated in an antero-ventricular junction 42 which extends laterally between the atrium 18,  
25 23, and ventricles 21, 25. The "base" of the inferior muscle is also in this general location. This wide base 35 extends to the apex 37 on the inferior cardiac surface. In the area of the base 35, the muscle is relatively flat or  
30 slightly spherical compared to the curvilinear form in the anterior wall. The muscle fiber orientation is maintained at approximately 60 degrees from base 35 to apex 37 to maintain the torsional gradient which facilitates ejection. This orientation of fibers changes to accentuate ejection,

with less twisting at the base 35 and more twisting at the apex 37.

On the backside, the heart 12 has an inferior wall 44 that is not curved or linear, but rather flat or slightly spherical in configuration. This inferior wall 44 extends  
5 from the antero-ventricular junction 42, at the wide area of the heart, toward the apex 37.

The pumping of the blood from the left ventricle 25 is accomplished by two types of motion. One of these motions  
10 is a simple squeezing motion which occurs between the lateral wall 38 and the septum 41 as illustrated by the arrows 43 and 45, respectively. The squeezing motion occurs as a result of a thickening of the muscle fibers in the  
15 myocardium. This compresses the blood in the ventricle chamber 25 and ejects it into the body 10. The thickening is reduced in diastole (when the heart is contracting) and increased in systole (when the heart is ejecting). This is seen easily by echocardiogram, and can be routinely  
20 measured.

In addition to the squeezing, there is a twisting of fibers that results in thickening of the ventricular wall, and shortening of the muscle from the base 35 to the apex  
25 37. This is the predominant aspect of left ventricle systole. The muscle untwists after twisting (when the heart is prepared to fill) during the first third of ventricular relaxation.

The twisting or writhing motion which begins at the  
30 apex 37 and rises toward the base 35, as shown by the arrow 47. The rising writhing motion occurs because the heart muscle fibers run in a circular or spiral direction around the heart 12. When these fibers constrict, they cause the

heart to twist initially at the small area of the apex 37, but progressively and ultimately to the wide area of the base 35.

Recent studies by MRI show that twisting in systole accounts for approximately 80% of stroke volume, while  
5 untwisting (in diastole) accounts for 80% of left ventricle filling. This twisting and untwisting occurs in the same muscle segments, as the ventricle shortens during ejection and lengthens after blood is ejected.

10 The amount of blood pumped from the left ventricle 25 divided by the amount of blood available to be pumped is referred to as the ejection fraction of the heart 12. Generally, the higher the ejection fraction the more healthy  
15 the heart. A normal heart, for example, may have a total volume of one hundred milliliters and an ejection fraction of sixty percent. Under these circumstances, 60 milliliters of blood are pumped with each beat of the heart 12. It is  
20 this volume of blood in the normal heart of this example, that is pumped with each beat to provide nutrients including oxygen to the muscles and other tissues of the body 10.

The muscles of the body, of course, include the heart muscle or myocardium which defines the various chambers  
25 18-25 of the heart 12. This heart muscle also requires the nutrients and oxygen of the blood in order to remain viable. With reference to Figure 2, it can be seen that the anterior or front side of the heart 12 receives oxygenated blood  
30 through a common artery 50 which bifurcates into a septal artery branch 52, which is directed toward the septum 41, and an anterior descending artery 54 which is directed toward the apex 37 and the lateral ventricle wall 38.

The inferior wall 44 is supplied by the right coronary artery which also perfuses the septum 41. This wall 44 forms a triangle which extends from the base 35 to the apex 37. Consequently, the apex 37 is supplied by both the anterior descending artery and the right coronary artery.

When a blockage occurs in one of these coronary arteries, that portion of the heart muscle which is fed by the blocked artery no longer receives the oxygen needed to remain viable. These blockages typically occur in the common artery 50 and in the septal artery branch 52. When the common artery is involved, the septum 41, apex 37 and lateral wall 38 all become ischemic or oxygen deprived. When only the septal artery branch 52 is involved, the ischemic symptoms are limited primarily to the septum 41 and the apex 37. In this latter case, the septum 41 is almost always affected, the apex 31 is usually affected, and the lateral wall 38 is sometimes affected.

As the ischemia progresses through its various stages, the affected myocardium dies losing its ability to contribute to the pumping action of the heart. The ischemic muscle is no longer capable of contracting so it cannot contribute to either squeezing or the twisting motion required to pump blood. This non-contracting tissue is said to be akinetic. In severe cases the akinetic tissue, which is not capable of contracting, is in fact elastic so that blood pressure tends to develop a bulge or expansion of the chamber. This is particularly detrimental as the limited pumping action available, as the heart 12 loses even more of its energy to pumping the bulge instead of the blood.

The body's reaction to ischemic infraction is of particular interest. The body 10 seems to realize that with

a reduced pumping capacity, the ejection fraction of the heart is automatically reduced. For example, the ejection fraction may drop from a normal sixty percent to perhaps twenty percent. Realizing that the body still requires the same volume of blood for oxygen and nutrition, the body  
5 causes its heart to dilate or enlarge in size so that the smaller ejection fraction pumps about the same amount of blood. As noted, a normal heart with a blood capacity of seventy milliliters and an ejection fraction of sixty  
10 percent would pump approximately 42 milliliters per beat. The body seems to appreciate that this same volume per beat can be maintained by an ejection fraction of only thirty percent if the ventricle 25 enlarges to a capacity of 140  
15 milliliters. This increase in volume, commonly referred to as "remodeling" not only changes the volume of the left ventricle 25, but also its shape. The heart 12 becomes greatly enlarged and the left ventricle 25 becomes more spherical in shape losing its apex 37 as illustrated in  
20 Figure 3. In this view, the stippled area of cross section shows the ischemic or infarcted region of the myocardium.

On the level of the muscle fibers, it has been noted that dilation of the heart causes the fibers to reorient  
25 themselves so that they are directed away from the inner heart chamber containing the blood. As a consequence, the fibers are poorly oriented to accomplish even the squeezing action as the lines of force become less perpendicular to the heart wall. It will be noted that this change in fiber  
30 orientation occurs as the heart dilates and moves from its normal elliptical shape to its dilated spherical shape. The spherical shape further reduces pumping efficiency since the fibers which normally encircle the apex to facilitate

writhing are changed to a more flattened formation as a result of these spherical configurations. The resulting orientation of these fibers produce lines of force which are also directed laterally of the ventricle chamber 25. Thus, the dilatation and resulting spherical configuration greatly  
5 reduce contraction efficiency. It also raises myocardial oxygen demands as torsional defamation (strain) increases. When a remote muscle is supplied by a non-occluded vessel under stress, the remote muscle tends to contract  
10 inefficiently.

Although the remodeling of the heart 12 by the body 10 helps in maintaining the blood flow, it places the heart wall under considerable stress which eventually can result in congestive heart failure. While myocardial ischemia or  
15 infarction is the primary cause of death and disability in this country, congestive heart failure is certainly the secondary cause with over 400,000 cases reported annually. It is this post-infarction congestive heart failure which is  
20 a primary focus of the present invention.

As noted, successful acute reperfusion by thrombolysis, percutaneous angioplasty, or urgent surgery can decrease early mortality by reducing arrhythmia and cardiogenic  
25 shock. These procedures applied in the early stages of ischemia can also aid in salvaging the epicardial surface of the myocardium and thereby prevent akinetic tissue from becoming dyskinetic. Notwithstanding these known methods of intervention, cardiac dilation and subsequent congestive  
30 heart failure occur in approximately fifty percent of the post-infarction patients.

Ventricular volume is not excessive or  $>100 \text{ ml/m}^2$  left ventricular end systolic volume. The akinetic lateral wall

may contain non-functional (contractile tissue) that is hibernating. This indicates viable tissue that improves contraction several months after complete revascularization or when ventricular volume is reduced to produce a more normal ventricular contour (i.e., ellipse). This recovery  
5 after revascularization can occur only when ventricular volume is not very large, or the left ventricular end systolic volume index  $>100 \text{ ml/m}^2$ . This aspect of recovery of akinetic hibernating muscle is potentially important when  
10 the ventricular shape is changed surgically to go from a sphere (failing heart) to a conical or apical (more normal configuration) contour.

The procedure of the present invention addresses the effects of myocardial infarction using a cardioprotective  
15 approach to restore the geometry of the left ventricle. This is not a "remodeling" procedure automatically produced by the body 10, nor a "reconstructive" procedure which leaves the heart with other than a normal geometry. Rather,  
20 this is a procedure which attempts to "restore" the normal geometry, and particularly the apical configuration of the left ventricle 25. The procedure reduces the volume of the left ventricle 25, but also increases the percentage of the  
25 ventricle wall which is viable. This greatly increases the ejection fraction of the heart and significantly reduces heart stress.

With a primary purpose of reducing the left ventricle volume, the intent of the procedure initially is to remove  
30 that portion of the wall which is not capable of contracting. This, of course, includes the scarred dyskinetic segments, which are easy to visualize, but may

also include akinetic segments, which do not contract despite their normal appearance.

5 An incision 61 is cut into the myocardial wall of the dilated heart 12 as illustrated in Figure 4. If the surrounding tissue is dyskinetic, it will typically be formed entirely of thin, elastic scar tissue. It is the elasticity of this scar tissue which causes the detrimental ballooning or bulging effects previous discussed.

10 In some cases, the tissue surrounding the incision 61 will be somewhat marbled as illustrated in Figure 5 with patches of both scar tissue 63 and viable red tissue 65. This marbled tissue is often characterized by trabeculae 67 which form ridges along the inner surface or endothelium of the wall. In spite of the presence of some viable tissue 15 65, these marbled walls of the heart 12 may nevertheless be akinetic.

20 With reference to Figure 6, it is apparent that the akinetic portion of the myocardium may even appear to be viable with an absence of white scar tissue and the presence of a full red color. Nevertheless, these portions are akinetic and offer no positive effect to the pumping process.

25 Given these factors, it is apparent that a determination as to where the akinetic portions begin and end cannot be a visual determination as relied on by the prior art. Although the visual appearance may be of some value in this determination, ultimately, one must palpate 30 the tissue as illustrated in Figure 7. Note that this emphasizes the importance of performing the restorative surgery on a beating heart. By palpating the myocardial wall, one can feel where the contractions of the lateral



ventricular wall 38 and the septum 41 begin and end. Without regard for color or other properties visually distinguishable, the palpating will usually indicate viable tissue on one side of an imaginary circumferential line 70, with akinetic and dyskinetic tissue on the other side of the imaginary line 70. As described in greater detail below, a patch 72 will ultimately be positioned relative to this imaginary circumferential line 70 not only to reduce the volume of the left ventricle 25 but also to define that reduced volume with a larger percentage of viable heart muscle.

After the preferred location of the patch 72 has been determined relative to the circumferential line 70, a continuous Fontan stitch 74 can be placed in proximity to the line 70 as illustrated in Figure 9. This stitch 74 produces an annular protrusion 76 which forms a neck 78 relative to the imaginary line 70. This neck 78 initially may have a round circular configuration as illustrated in Figure 9. However, as the suture 74 is tightened, the musculature of the myocardium will form a natural oval shape as illustrated in Figure 11. It is this oval-shaped neck 78, formed by the Fontan stitch 74, which in its natural ovoid shape is particularly adapted to receive the patch 72 of the present invention.

Providing the patch 72 with a configuration complimentary to the ovoid shape of the Fontan stitch 74 is believed to be of particular importance and advantage to the present invention. In the past, patches of a round, circular form were used. This form maintained the fibers in their less efficient transverse orientation. This was especially true of rigid and semi-rigid patches. As a

result, the fiber contraction continued to be very inefficient. Providing the patch with an oval configuration restores the apex 37 or elliptical form of the heart 12. On a muscle fiber level, the fibers are directed back to the more efficient 60 degree orientation which produces lines of force more perpendicular with respect to the heart wall 38. This reorientation of the lines of forces greatly increases contraction efficiency.

Of perhaps equal concern is the use of semi-rigid or rigid rings on the patches of the past. By keeping the edges of the patch in a rigid configuration, these rings have inhibited the natural tendency of the heart to form the remaining muscle into a normal apical chamber.

Construction of various embodiments of the patch 72 are discussed with reference to Figures 12A-20. In the plan view of Figure 12A, a sheet material 81 is illustrated to have the shape of an ellipse with a major axis 83 between 30 and 50 millimeters and a minor axis 85 between 20 and 30 millimeters. It is contemplated that the sheet material 81 can be provided in two sizes, such as 20x30 millimeters and 30x40 millimeters.

The sheet material 81 may be formed, for example, from Dacron (Hemoshield), or polytetrafluoroethylene (Gortex). However, in a preferred embodiment, the sheet material 81 is formed of autologous pericardium, or some other fixed mammalian tissue such as bovine or porcine pericardium. Importantly, the sheet material 81 is preferably sized and configured with a shape similar to that of the Fontan neck 78 as illustrated in Figure 11. As noted, this shape is non-circular and preferably oval.

The sheet material 81 can have a generally flat planar configuration, or can be shaped as a section of a sphere. The spherical shape can be achieved as illustrated in Figure 12B by fixing the pericardium while it is stretched over a spherical die to form a concave surface 90.

5 In addition to the sheet material 81, the patch 72 also preferably includes a ring 87 which will typically have a toroidal configuration with a circumferential cross section that is circular, as shown in Figure 13. The ring will typically be formed of a plastic graft material that can also be made of curled autogenous tissue such as fascia or pericardium. In general, the ring 87 can be formed from any biocompatible material having a degree of flexibility  
10 suitable to prevent interference with the normal  
15 contractions of the heart 12.

The circumferential cross section view of Figure 14 illustrates that the ring 87 may be enclosed in a tubular sheath 90 which may be formed from woven Dacron, and  
20 incorporated to promote tissue ingrowth to the patch 72.

The ring 87 will generally have a non-circular shape which may be similar to but smaller than the shape of the material 81. Providing the ring 87 with a shape similar to  
25 the material 81 will enable the ring 87 to be attached to the material 81 as illustrated in Figures 15 and 16 with a body 91 of the patch disposed within the ring 87, and a circumferential rim or flange 93 disposed outwardly of the ring 87. The rim 93 will preferably have a constant width  
30 around its circumference. This width will typically be in a range between 5 and 8 millimeters.

Many variations on the patch 72 will be apparent from the foregoing discussion. For example, as illustrated in

Figure 17, the sheet material 81 can be provided with a convex surface 95 facing the left ventricle 25 rather than the concave surface illustrated in Figure 13. As illustrated in claim 18, the ring 87 can be disposed on either the interior or exterior side of the material 81.

5       The ring 87 can be attached to the material 81 by adhesive or by stitches 97 passing over the ring 87 and through the material 81. Alternatively, the ring 87 can be sandwiched between two pieces of the sheet material. In  
10       this case, a second piece of the sheet material 99 can be positioned on the side of the ring 87 opposite to the sheet material 81. Appropriate sutures extending around the ring 87 and through the materials 81 and 99 will sandwich the  
15       ring and maintain it in the preferred position. The second piece of material 99 can be formed as a circle with an inner diameter 100 less than that of the ring 87, and an outer diameter 102 generally equal to that of the material 81.

20       It will be appreciated that many variations on these preferred embodiments of the patch 82 will be apparent, each having a generally non-circular sheet material, such as the material 81, and perhaps a somewhat flexible toroid or oval ring 87.

25       In a preferred method for placing the patch 72, interrupted sutures 105 can be threaded through the Fontan neck 78 as illustrated in Figure 21. Where the tissue is soft, the sutures 105 can be looped through pledgets 110 on  
30       the interior side of the neck 78 with the free ends of the sutures 105 extending through the exterior side of the neck 78. These free ends, emanating from progressive positions around the circumferential neck 78, are passed in complementary positions through the body of the patch 72

which is initially positioned remotely of the neck 78 as illustrated in Figure 21. Since the Fontan stitch 74 maybe applied to normal (although akinetic) tissue, the pledgets 110 are preferred to insure that the sutures 105 are well anchored in the neck 78.

5           Another method for placement of the interrupted patch suture is illustrated in Figure 22B. In this view, which is similar to Figure 51, interrupted sutures 111 are directed through the entire ventricular wall 38 and exit the wall 38  
10 in proximity to the protrusion 76 which forms the Fontan neck 78. These sutures 111 can also be anchored in a pledged strip 113 disposed on the outer surface of the heart 12 to further enhance the anchoring of these sutures 111.

15           When all of the interrupted sutures 105 have been placed around the circumference of the neck 87, the patch 72 can be moved from its remote location along the sutures 105 and into proximity with the oval neck 78. This step is illustrated in Figure 22 where the patch 72 is embodied with  
20 the concave surface 90 facing the neck 78 and with the ring 87 disposed outwardly of the material 81. After the patch 17 has been moved into an abutting relationship with the neck 78, the interrupted sutures 105 can be tied as  
25 illustrated in Figure 23.

          Having closed the left ventricular cavity 25 with the patch 72, one may proceed to address any bleeding which may have resulted from placement of the Fontan stitch 74 or the sutures 105, especially from the region of the septum 41.  
30 Such bleeding, illustrated by the reference numeral 112 in Figure 23, will typically occur in close proximity to the neck 78 and beneath the region covered by the rim or flange 93 associated with the material 81 of the patch 72. This

bleeding can normally be stopped by merely placing a suture through the ventricular wall 38 and the rim 93 at the point of bleeding. A pledget 114 can be used to tie the suture 112 with the rim 93 closely held against the bleeding wall 38. This reinforcing stitch, acting in combination with the rim 93 of the patch 72, will usually stop any bleeding associated with the sutures.

With the patch 72 suitably placed, the operative site can be closed by joining the myocardial walls in a pants-over-vest relationship as illustrated in Figure 24. Care should be taken not to distort the right ventricle 21 by folding the septum over the wall 41 ventricular wall 38. Alternatively, the lateral wall 38 can be disposed interiorly of the septum wall 41 so a majority of the force on the patch 72 is diverted to the lateral wall 38. These walls 38 and 41 can be overlapped in close proximity to the patch 72 in order to avoid creating any cavity between the patch 72 and the walls 38, 41. When air evacuation is confirmed by transesophageal echo, the patient can be weaned off bypass usually with minimal, if any, inotropic support. Decanulation and closure is routine.

Figure 24 is positioned in proximity to Figure 3 in order to illustrate the dramatic difference between the pre-operative dilated heart of Figure 3 and the post-operative apical heart of Figure 24. For comparison it will again be noted that the dilated heart of Figure 3 might typically have a left ventricular volume of 140 milliliters which might produce a blood flow of 42 milliliters with an ejection fraction of 30%. Comparing this with the postoperative heart of Figure 24, it can be seen initially that the ventricular volume is reduced for example to 90

milliliters. The percentage of viable heart wall as opposed to akinetic heart wall is greatly increased thereby providing an increase in the ejection fraction, for example from thirty percent to forty-five percent. This combination results in a pumped blood volume of about 40 milliliters with each beat of the heart 12.

These structural changes are somewhat quantitative in consideration. But a further advantage, qualitative in nature, is also associated with the present procedure. It will be noted that this restorative procedure provides the heart 12 with a more natural apical configuration which facilitates the writhing action discussed with reference to the arrow 47 in Figure 1. Thus, not only is the normal size of the heart achieved, but the restoration procedure also achieves a normal heart operation. In combination, the patch 72 and the resulting procedure significantly reduce the long term effects of myocardial ischemia and overcome many of the causes associated with congestive heart failure.

It may be found that muscle function will be restored to some remote areas following the altered ventricular architecture. Although not fully understood, it is believed that this restoration procedure improves remote segmental myocardial contractility by reducing the wall tension and stress in the myocardium due to a reduction in ventricular volume. The stress equation states that --

$$\text{Stress} = \frac{P \times R}{2h}$$

where

P is blood pressure;

R is radius of the heart wall; and

h is wall thickness.

The late recovery of hibernating muscle, which may be present in akinetic muscle whose fiber orientation is directed helically (toward the newly created apex). This progressive shape change may provide further improvement in contractile function several months after restoration. Reducing the ventricular volume decreases the radius, increases the thickness, and thereby reduces wall stress. This improves the myocardial oxygen supply/demand relationship, but may also revive the contractibility of otherwise normal but previously stressed myocardium. At the very least, the reduced stress on the heart is relieved along with any potential for congestive heart failure.

A further advantage of this procedure relates to the incision 61 in the left ventricle 25 which also provides access to the mitral valve 34. Replacing this mitral valve 34 through the left ventricle 25 is much simpler than the present intra-aortic replacement procedure. Coronary artery bypass grafts also can be more easily accommodated intraoperatively. As a result, all of these repairs can be undertaken with greater simplicity and reduced time. While blood cardioplegia may be advantageously used for revascularization and valvular procedures, it would appear that the restorative procedure is best accomplished with continuous perfusion of the beating open heart for cardiac protection.

Placement of patch 70 can be further enhanced by providing in the patch kit a plurality of sizing disks which can be individually held in proximity to the Fontan neck in order to determine appropriate patch size. Similar discs,



triangular in shape may be used for the inferior restoration process. The disks might have a generally planar configuration, and of course, would vary in size. Each disk might have a centrally located handle extending from the planar disk for ease of use. The patch 72 could be  
5 removably mounted on a holder also including a disk, on which the patch is mounted, and an elongate handle extending from the disk to facilitate placement.

A procedure similar to that previously discussed with respect to the anterior patch 72 can be used to restore  
10 ventricular architecture to the inferior wall 44 of the heart 12. This procedure is illustrated in the progressive views of Figures 25-31.

Figure 25 illustrates the inferior wall 44 after the heart 12 has been lifted from the patient's chest and the apex 37 rotated upwardly, generally about the base 35 of the heart 12. Thus, the base 35 which is normally above the apex 37 is illustrated below the apex 37 in Figure 25.  
15 Extending along the inferior wall 44 is the right coronary artery 120 which branches into the posterior descending artery 122. A blockage or occlusion 126 in the right coronary artery has resulted in ischemia producing a non-  
20 contractive region 128 which is illustrated by shading in Figure 25. It is the purpose of this procedure relating to the inferior wall 44 of the heart to remove the non-  
25 contracting muscle of the region 128 from the ventricle and to restore the ventricular architecture as previously  
30 discussed.

This procedure is continued as illustrated in Figure 26 by creating an incision in the inferior wall 44 in order to expose an inner surface 131 of the wall 44 and the interior

regions of the left ventricle 25. Opening the incision exposes the septum 41 and an annulus or base 133 associated with the mitral valve 34. The incision will typically be made along the non-contracting region 128 from a papillary muscle 135 near the apex 37 to the annulus 133 of the mitral valve 34.

As the incision is opened and the non-contracting regions 128 on either side are laid back, a line of separation 137 can be located between the non-contracting region 128 and contracting regions designated generally by the reference numeral 140. Basting sutures 142 are placed generally along this line of separation 137. These basting sutures 142 include a base suture 144 which extends between pledgets 146 and 148 along the base 37. Similarly, lateral basting sutures 148 and 151 can be placed to extend along the line of separation 137 between pledgits 153 and 155, and pledgets 157 and 160, respectively. In a preferred orientation, the lateral basting sutures 148 and 151 meet at a basting apex 162 and diverge to individually intersect the basting sutures 142 at the base 37. Thus, the basting sutures 142, 148 and 151 form a triangle along the line of separation 137.

A patch 171 similar to the patch 72 previously discussed can be configured as illustrated generally in Figure 28. This patch 171 can be formed from a sheet 173 of biocompatible material and a continuous ring 175 such as the ring 87 previously discussed.

With the inferior patch, the conical form is unnecessary and a more planar or spherical configuration is preferable. This configuration helps form the desired triangular contour for the inferior wall 44.

With the inferior patch 171, the sheet material 173 can be made of pericardium or Dacron or fascia. The preferred material will be similar to that of the apical patch previously discussed, but can be autogenous, bovine, or porcelain pericardium. The sheet material 173 will preferably have a triangular shape as will the ring 175. In a preferred embodiment, the shape of the ring 175 is geometrically similar to that of the sheet material 173. Thus, when the ring 175 is disposed centrally of the sheet material 173, it defines a central area 177 and a circumferential rim 179 having a generally constant width around the central area 177. In preferred embodiments, the triangular central area 177 will have sizes such as 2x3x1 and 3x4x1. The width of the circumferential rim 179 will typically be in a range between 1 and 2 centimeters.

This patch 171 is particularly adapted for placement across the triangular opening defined by the basting sutures 142, 148 and 151 as illustrated in Figure 28.

In a preferred method, the ring 175 is sewn to the neck formed by the basting sutures 142, 148 and 151 by sutures 180 extending interiorly through pledgets 182. Similar sutures 183 can be placed to extend entirely through the inferior wall 44 and an exterior pericardial strip 184 in proximity to the lateral basting sutures 151.

With the patch 171 thus positioned, as illustrated in Figure 30, the central area 177 partially defines the left ventricular chamber 25. However, the circumferential rim 179 remains exteriorly of the chamber 25 and extends along the inner surface 131 of the non-contracting region 128.

In a further step of this procedure illustrated in Figure 30, the circumferential rim 179 can be fixed to the

inner surface 131 by a running suture 186. In the manner previously discussed the circumferential rim 179 thus sutured to the non-contracting region 128 will inhibit any bleeding which may result from placement of the basting sutures 142, 148, 151 or the sutures 180 and 183 associated with placement of the patch 171.

By excluding the non-contracting region 128 and retriangulating the contracting tissue in the region 140, placement of the patch 171 facilitates restoration of the ventricular architecture along the inferior wall 44 of the heart 12.

As further support for the restoration procedure, a special suture needle is contemplated which has a proximal end and a distal end. The proximal end is generally straight and accounts for more than half of the length of the needle. The distal end is curved along a relatively large radius facilitating initial penetration of the thick heart wall. Placement of suture 183 can be further enhanced by providing in the patch kit a plurality of sizing disks which can be held in proximity to the triangulation suture in order to determine appropriate patch size. With this configuration, the needle can be easily introduced through the thick myocardium, but then pulled along a generally straight path as it is removed interiorly of the ventricle.

The goal of these procedures is to restore the heart 12 to its normal size, shape and function. This includes restoring the conical apex of the heart in order to achieve the writhing pumping action, and retriangulating the inferior (or diaphragmatic) segment. The nonfunctioning segmental ventricular myocardium is excluded and replaced with a patch so that the only akinetic wall of the ventricle

is that defined by the small patch area. Not only is visual assessment enhanced, but more importantly, palpation affords the surgeon the ability to carefully and accurately determine the circumferential line of separation between the contracting and noncontracting muscle. This determination is achieved although the muscle may have normal color and may not contain either circular or trabecular scar tissue.

It is believed that cardioplegia arrest may be deleterious to ventricular function in the open ventricle because of nonuniform flow distribution. By avoiding this cardioplegia arrest and operating on a beating heart, aortic cross clamping as well as the use of inter-aortic balloons and ventricular assist devices can be avoided. Patch placement can be intraoperatively adjusted guided by echo or radio nucleotide data. Placement of the patch is further simplified by creation of the Fontan neck 78 or triangular neck 175, and use of interrupted felt or pericardial pledgeted sutures 105. The circumferential rim 93 associated with the patch 72 facilitates bleeding control without distortion of the patch 72. Finally, using a pants-over-vest closure of the excluded ventricle obliterates dead space and provides security against patch leaks and resultant expansion between the site of closure of the ejecting ventricle with the patch, and where the excluded muscle is closed by the excluded ventricle.

If the patch has a conical or elliptical contour, the pants-over-vest closure is excluded, so that progressive recovery of potentially hibernating muscle (previously akinetic) can occur so that the muscle itself forms the apex. The pants-over-vest closure may prevent this, and that is the reason for excluding it.

Within these wide objectives and parameters, there will be variations on the structure of the patch and the methods of restoration. Although the non-circular configuration of the sheet material and ring are believed to be critical, the shape of the patch 72 may vary widely to provide the best anatomical fit with the natural shape of the ventricle 25. The sheet material 81 may be composed of a variety of materials, both natural and artificial. These materials may be woven or nonwoven to achieve a desired structure for the sheet material 81. The ring 87 may similarly be formed from a variety of materials and provided with a variety of shapes in order to add structure to the patch 72 without interfering with the normal contractions of the heart 12. Variations of the steps of the associated restoration method might include mounting the patch with a convex surface facing the ventricular cavity, use of tissue adhesives are also contemplated for attaching sealing and otherwise fixing the patch 72 to the Fontan neck 78 or the triangle 175.

Given these wide variations, which are all within the scope of this concept, one is cautioned not to restrict the invention to the embodiments which have been specifically disclosed and illustrated, but rather encouraged to determine the scope of the invention only with reference to the following claims.

Claims

1. A ventricular patch adapted for placement relative to the inferior wall of the heart, comprising:
  - 5 a sheet of biocompatible material having a generally planar configuration and the shape of a first triangle;
  - a continuous ring fixed to the sheet and having the shape of a second triangle geometrically similar to the first triangle;
  - 10 the ring defining a central region of the patch interiorly of the ring and a circumferential region of the patch exteriorly of the ring; and
  - the circumferential region of the patch having a generally constant width around the central region of the patch.
  - 15
2. The ventricular patch recited in claim 1, wherein;
  - the first triangle has a base with a length and the
  - 20 ratio of the constant width of circumferential region to the length of the base is in a range between 1 and 2.
3. The ventricular patch recited in claims 1 or 2, wherein the first triangle has three sides with associated lengths
- 25 in ratios of about 2 to 3 to 1.
4. The ventricular patch recited in claims 1, 2, or 3, wherein the first triangle has three sides with associated
- 30 lengths in ratios of about 3 to 4 to 1.
5. The ventricular patch recited in claims 1, 2, 3, or 4, wherein the bio-compatible material includes at least one of pericardium, Dacron and fascia.

6. The ventricular patch recited in claims 1, 2, 3, 4, or 5, wherein the pericardium is one of autologous, bovine, and porcine.

5 7. A method for restoring the ventricular architecture of a heart having an anterior wall and an inferior wall, comprising the steps of:

creating an incision in the inferior wall of the heart to expose an inner surface of the ventricle of the heart;  
10 forming a suture line around the inner surface of the inferior wall;  
providing a ventricular patch; and  
sewing the ventricular patch to the inner surface of the inferior wall along the suture line to restore the  
15 ventricular architecture of the heart.

8. The method recited in claim 7, wherein the providing step includes the step of  
20 forming the ventricular patch to include a sheet of biocompatible material and a continuous ring fixed to the sheet.

25 9. The method recited in claims 7 or 8, wherein the creating step includes the steps of  
creating the incision in a non-contracting region of the inferior wall;  
opening the incision to expose an inner surface of the  
30 heart, the contracting region being separated from the non-contracting region by a line of separation.



10. The method recited in claim 9, wherein the forming step includes the step of

forming the suture line generally along the line of separation.

5 11. The method recited in claims 8, 9, or 10, wherein the forming step includes the step of:

attaching the ring to the biocompatible material so that the ring defines a central area of the material  
10 inwardly of the ring and an outer rim of the material outwardly of the ring.

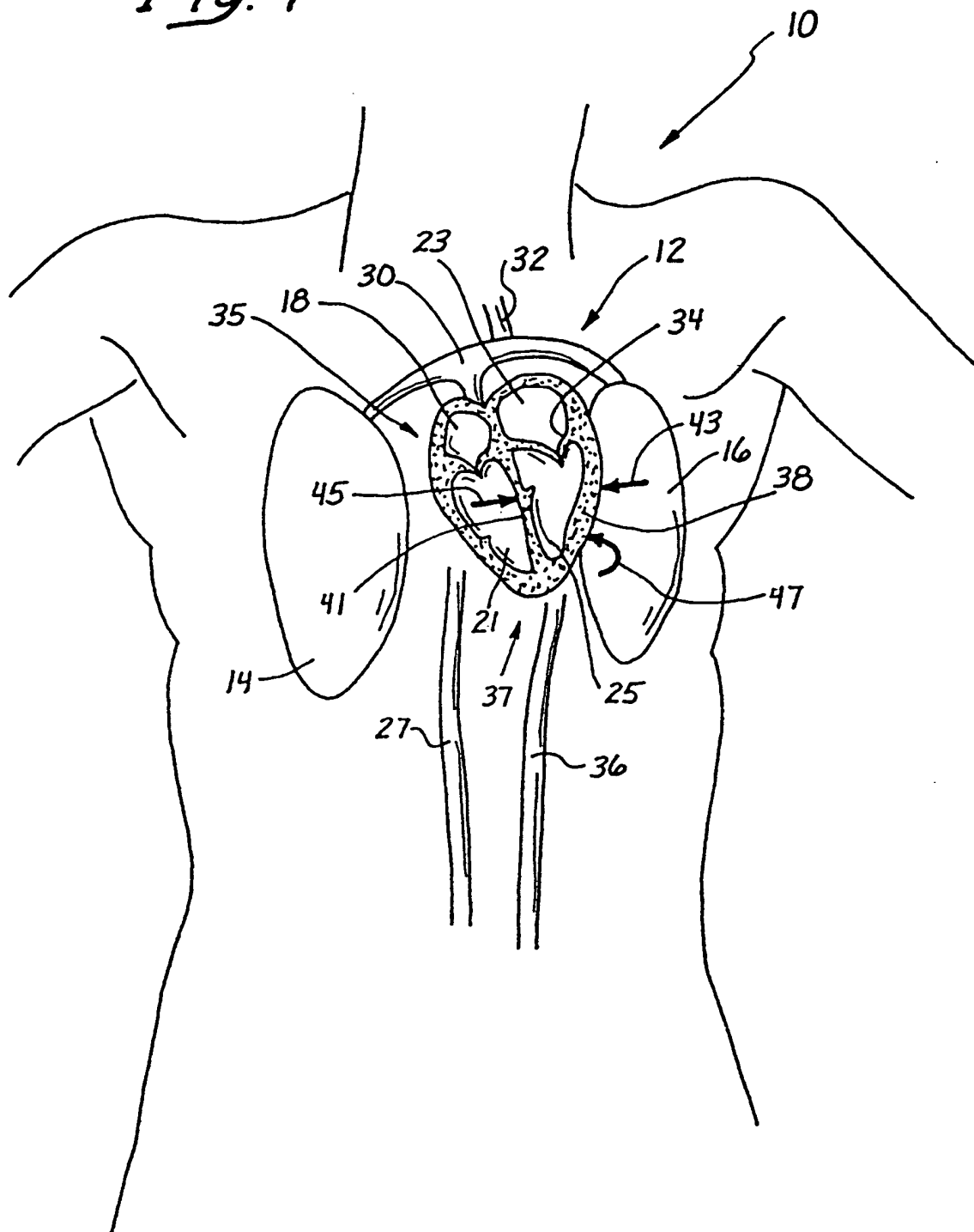
12. The method recited in claim 11, wherein the attaching step includes the step of:

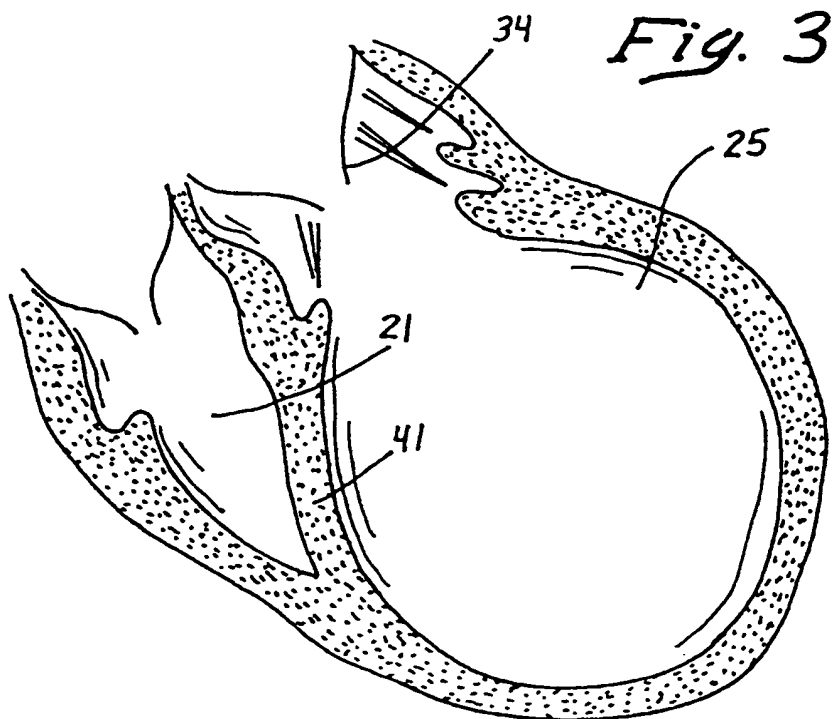
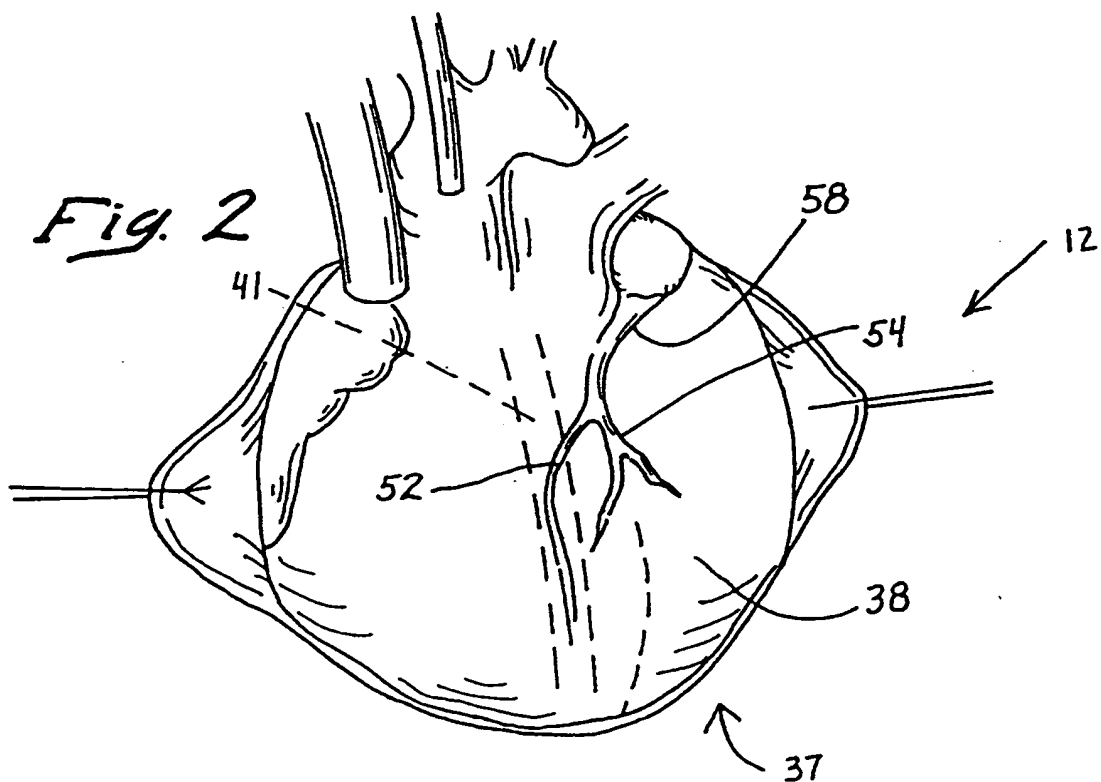
15 sewing the continuous ring to the inner surface of the ventricle so that the central area of the material defines a portion of the ventricle of the heart; and

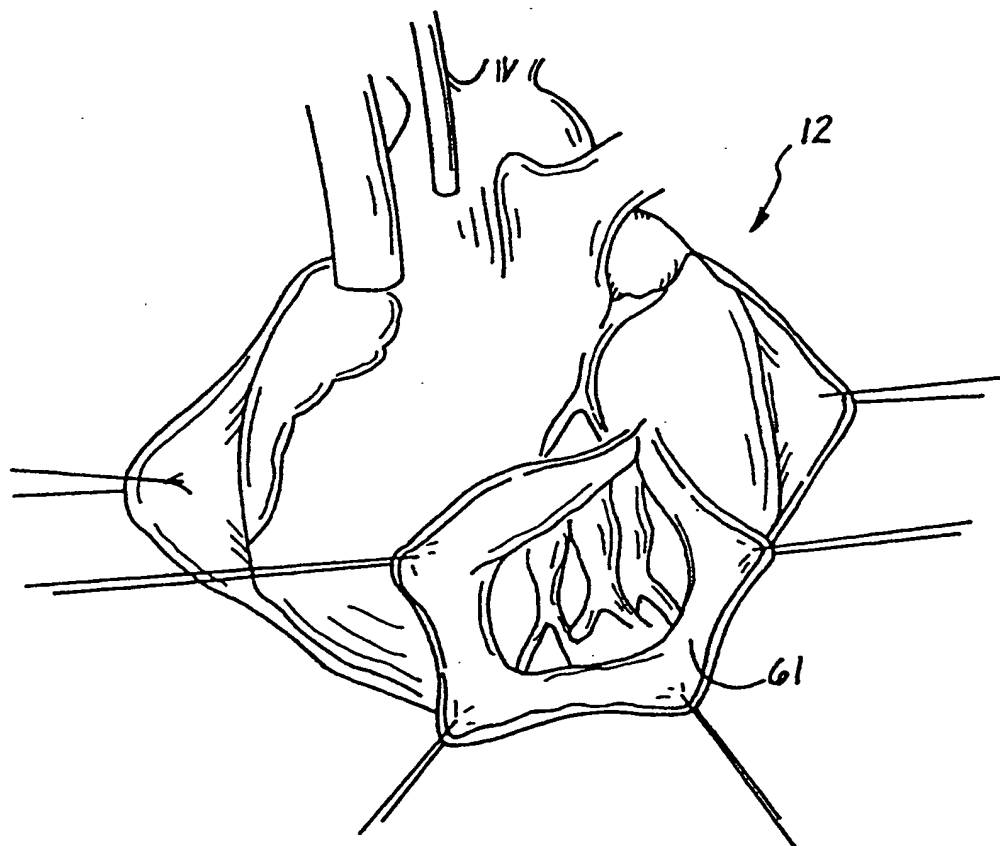
sewing the outer rim to the inner surface of the  
20 ventricle outwardly of the ventricle of the heart.

13. The method recited in claims 9, 10, 11, or 12 wherein the opening step includes the step of spreading the incision to create a triangular opening extending into the ventricle  
25 of the heart.

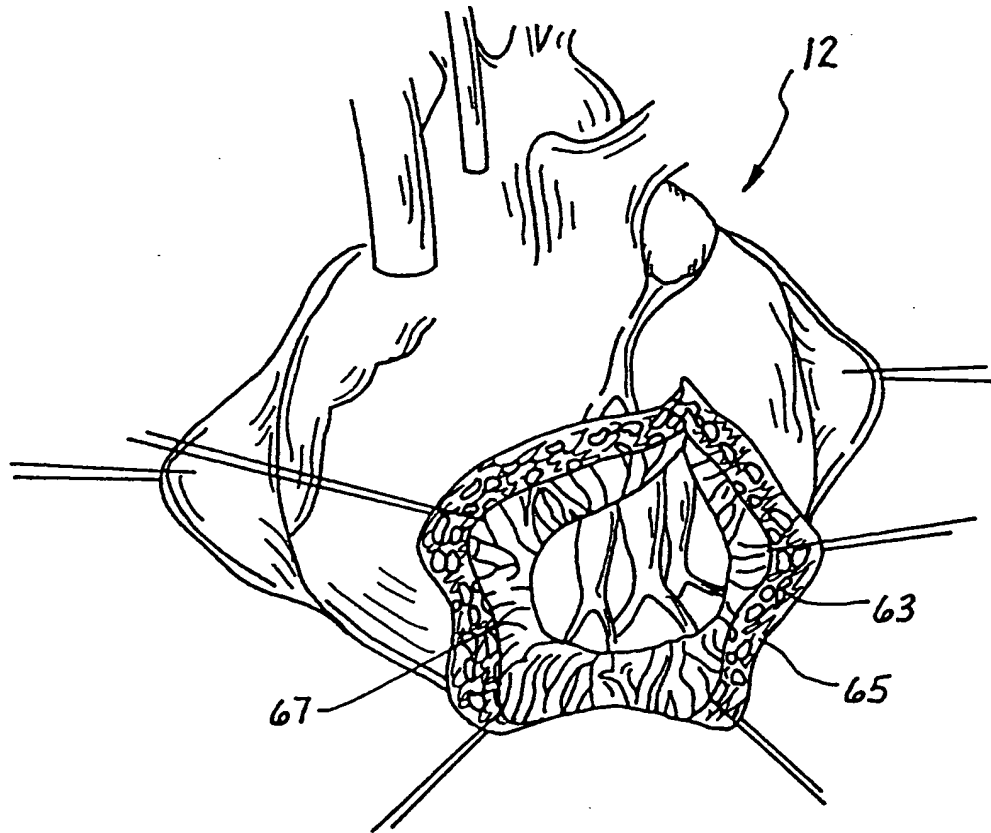
14. The method recited in claims 8, 9, 10, 11, 12, or 13, wherein the forming step includes the step of forming the  
30 biocompatible material and the continuous ring in the shape of a triangle.

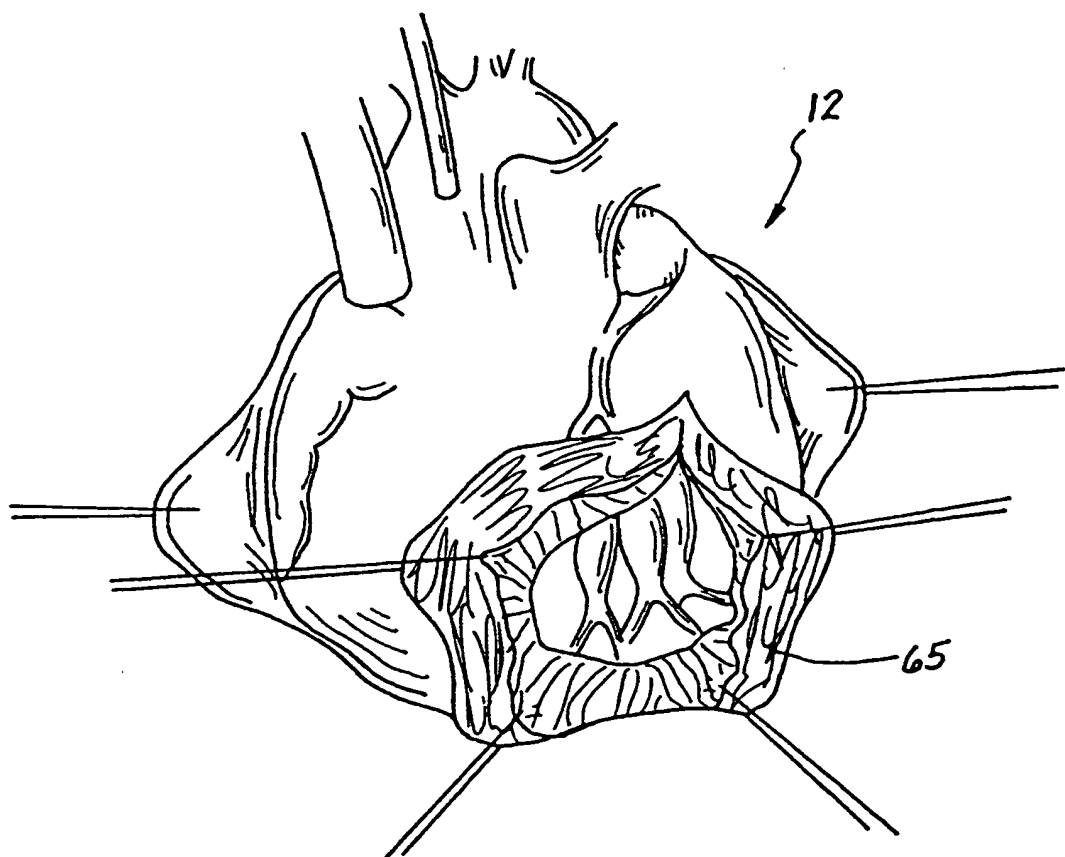
*Fig. 1*



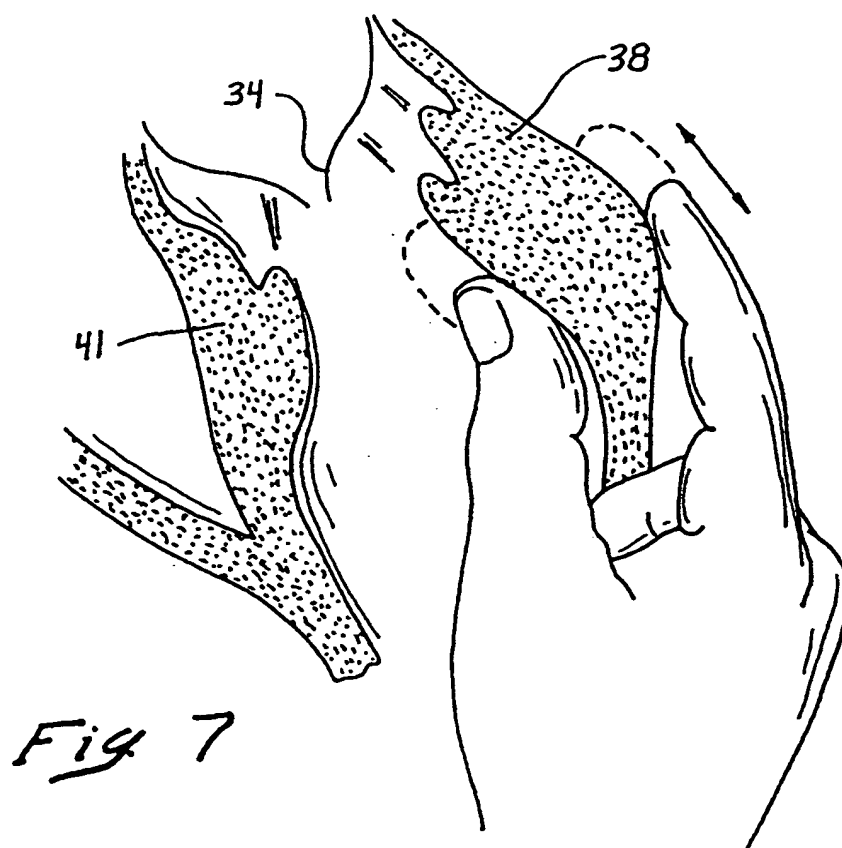
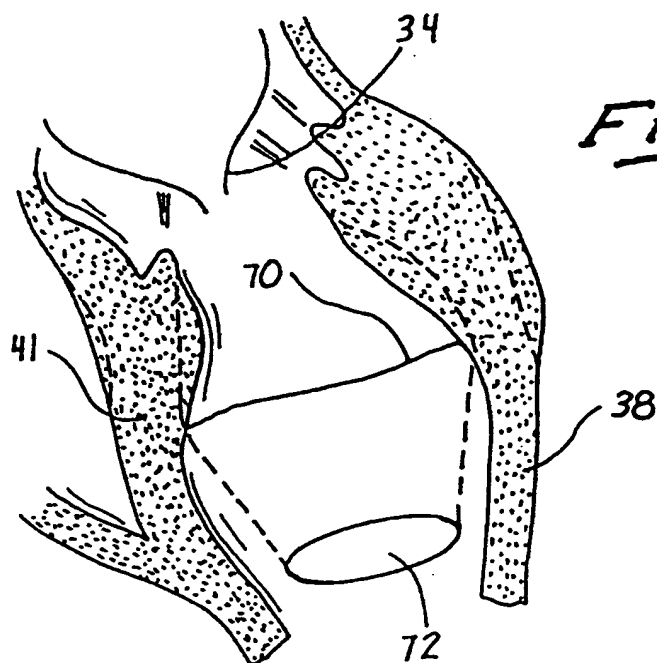


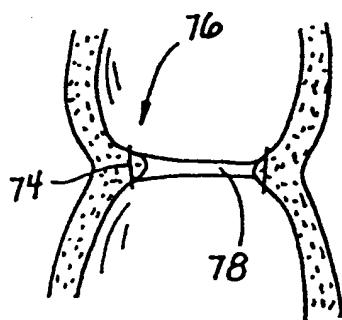
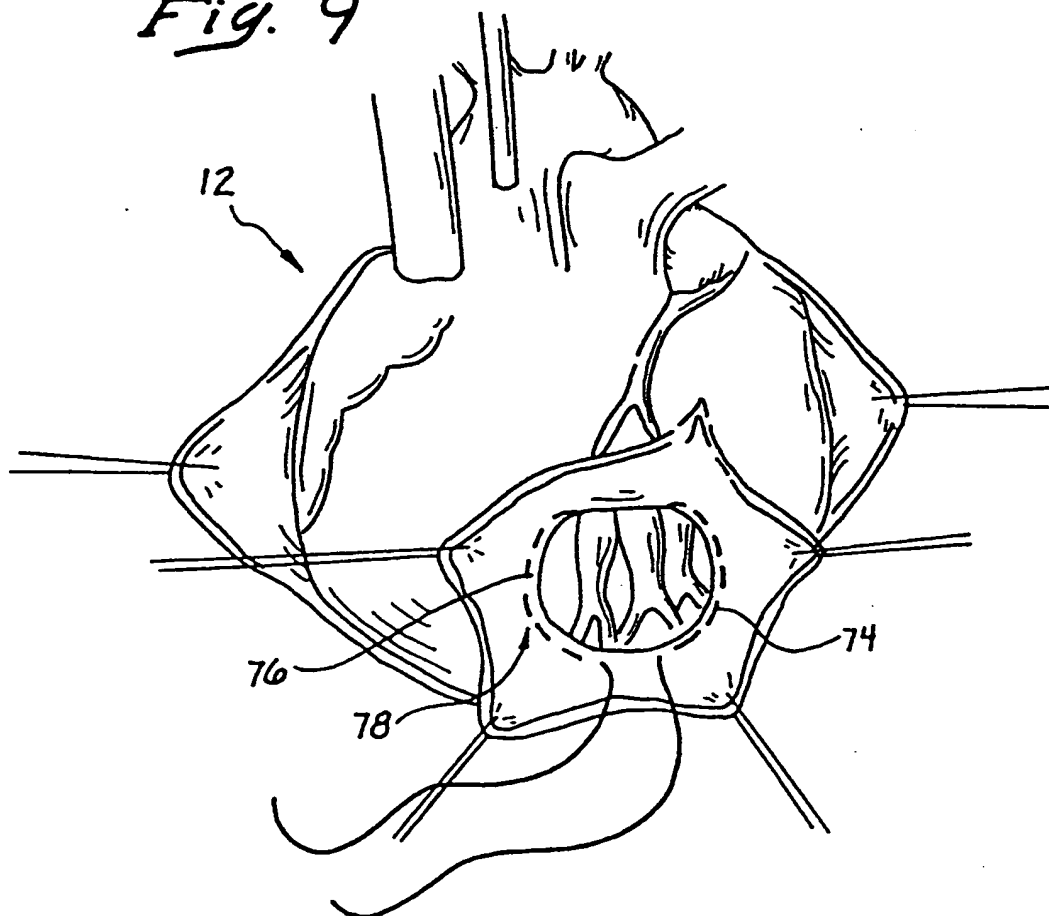
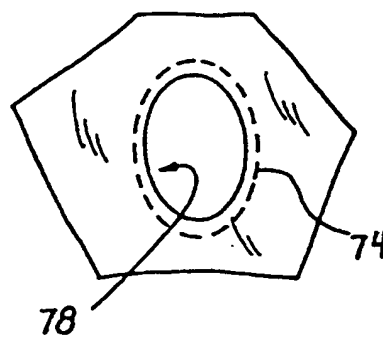
*Fig. 4*

*Fig. 5*

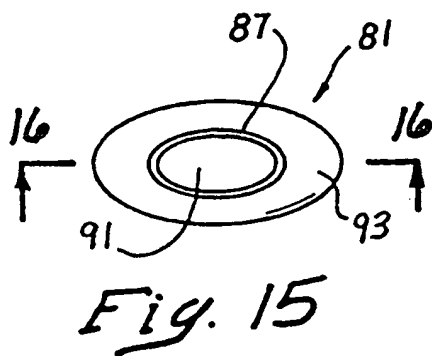
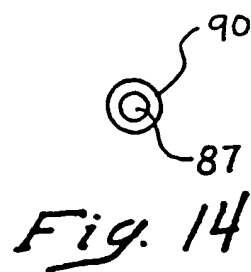
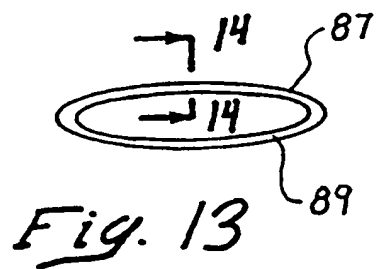
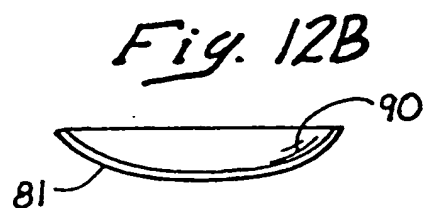
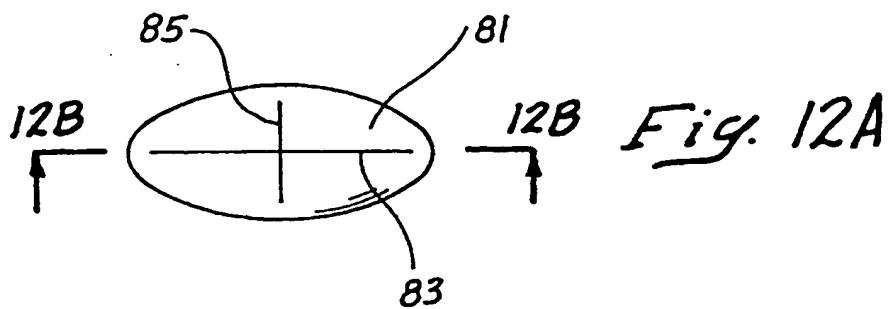


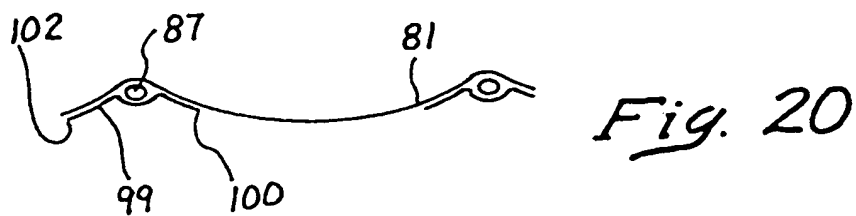
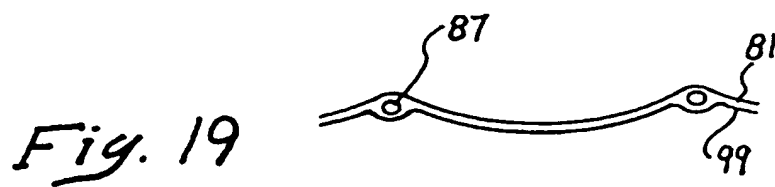
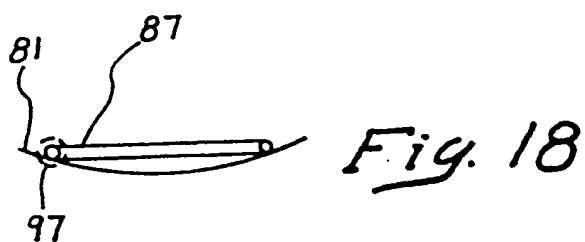
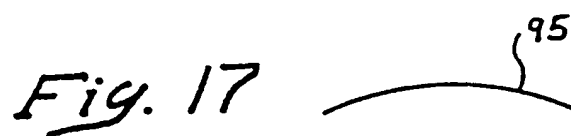
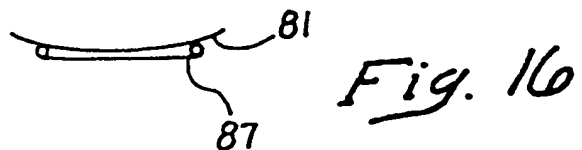
*Fig. 6*

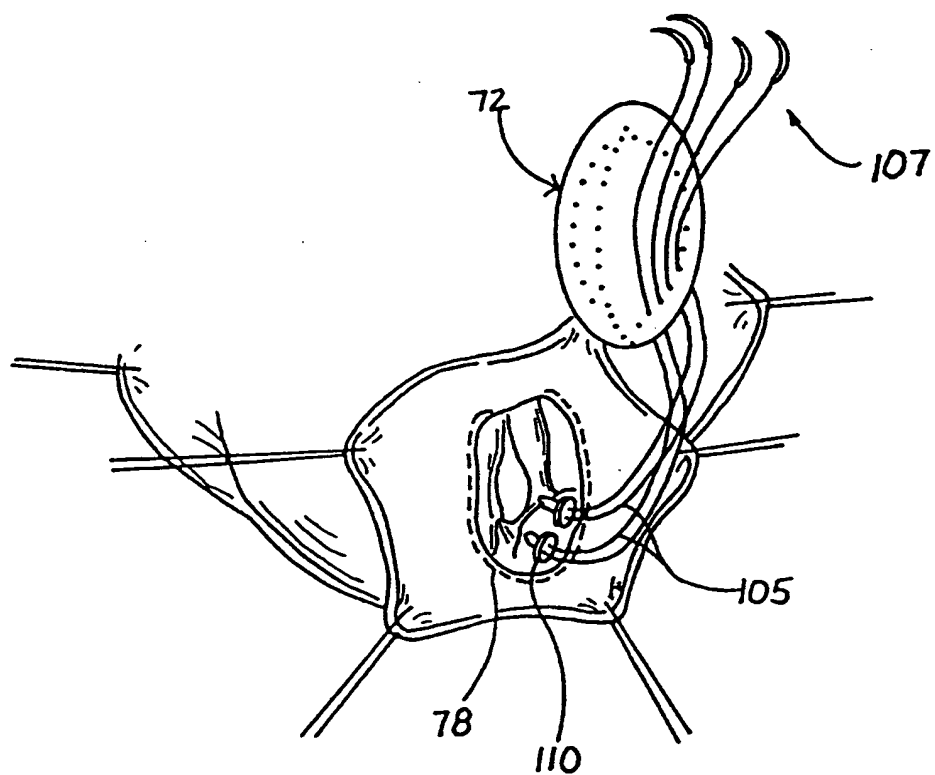


*Fig. 9**Fig. 10**Fig. 11*

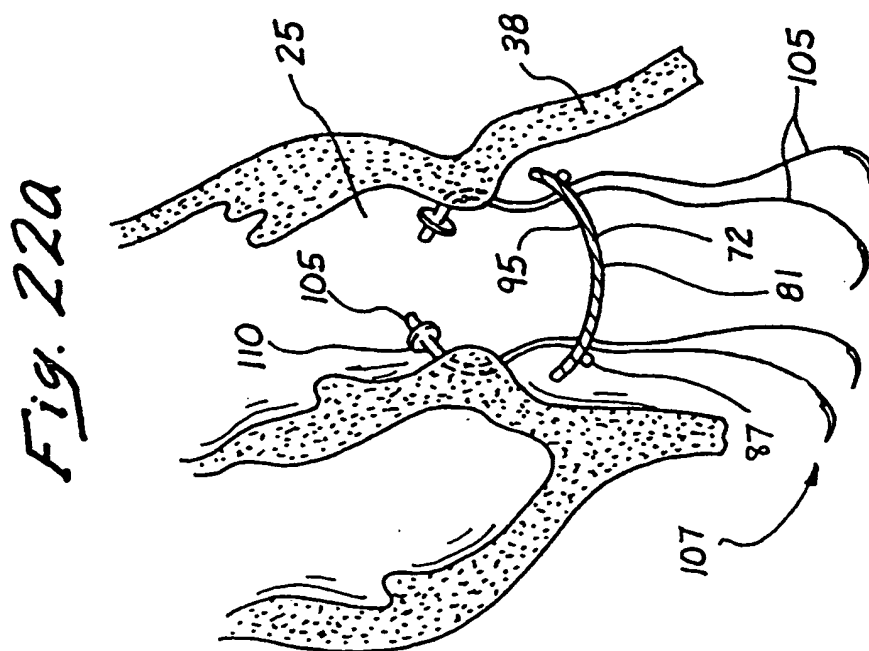
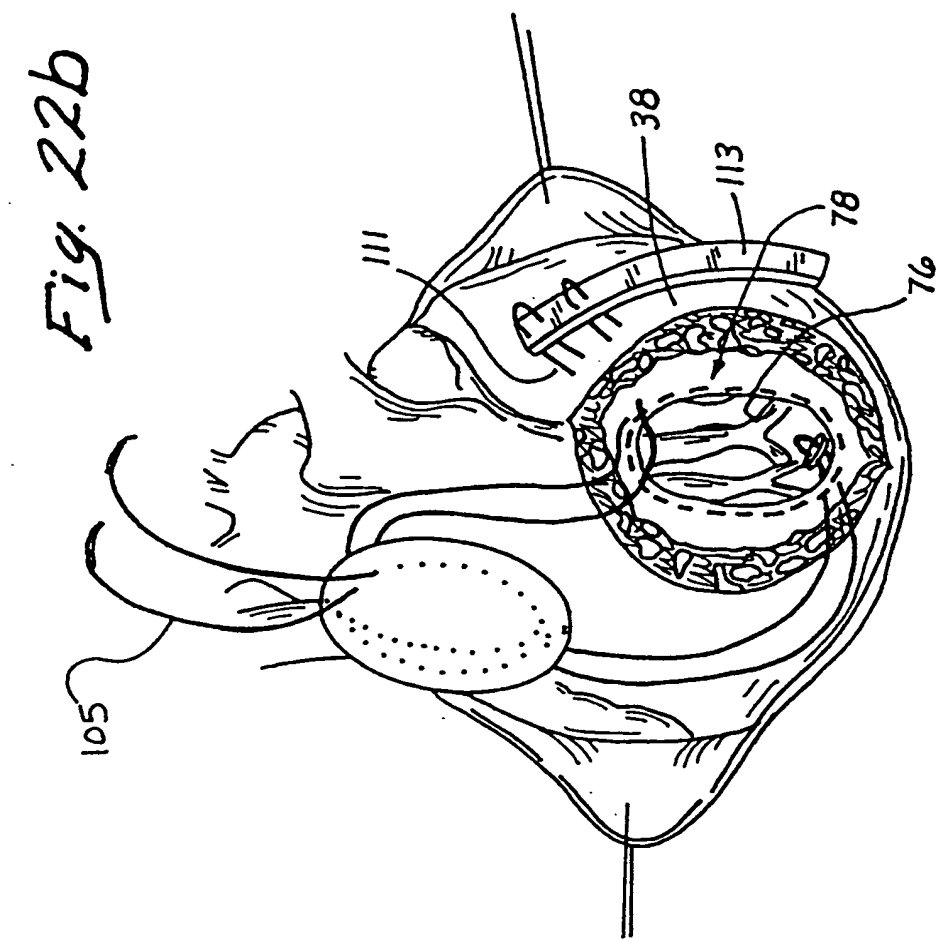


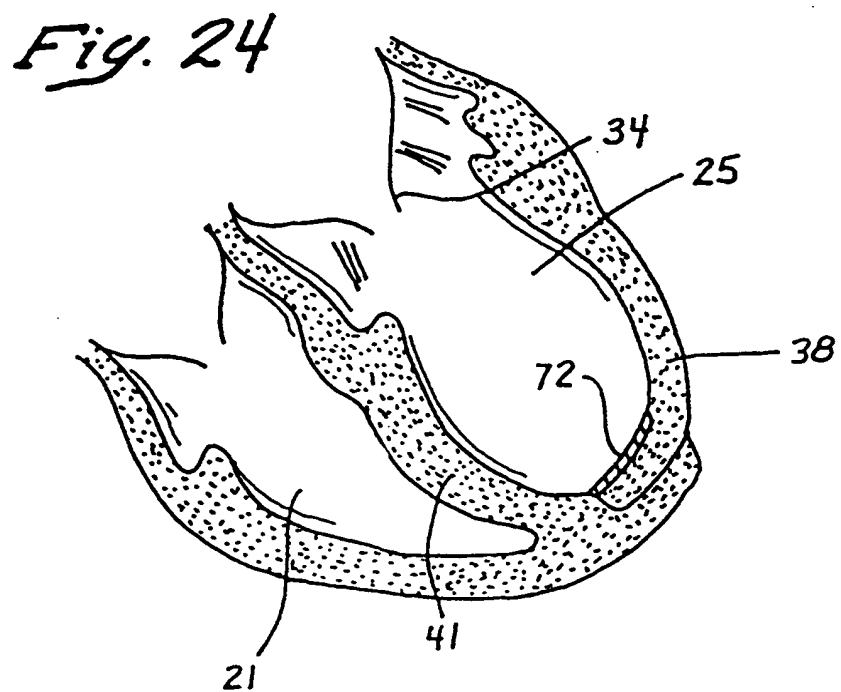
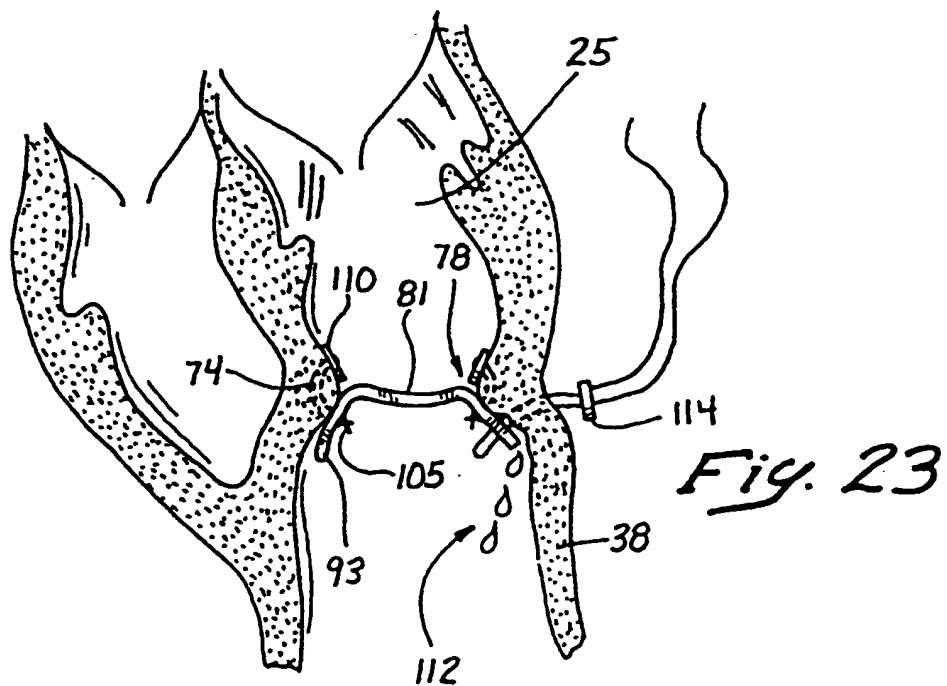




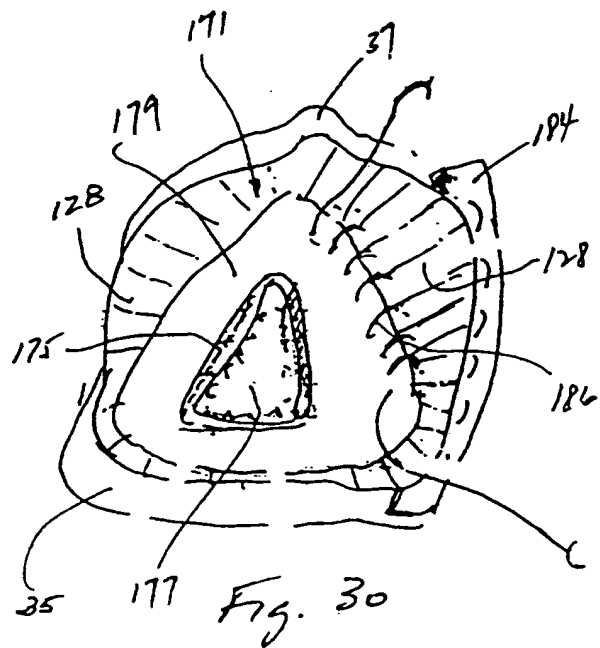
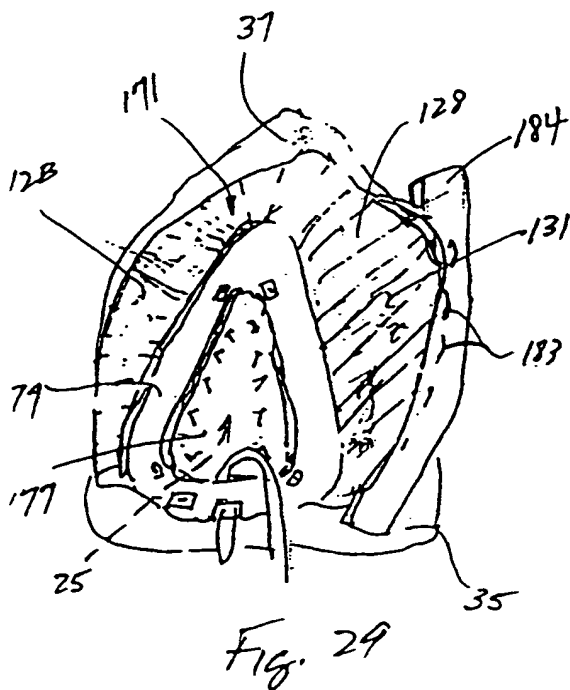
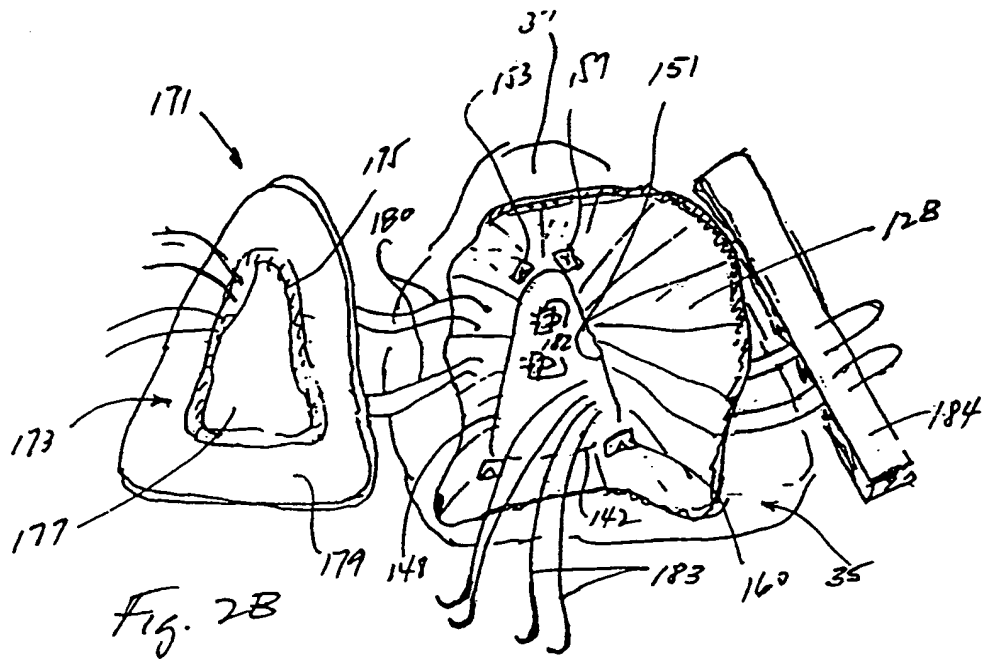


*Fig. 21*









## INTERNATIONAL SEARCH REPORT

Int. l. Application No

PCT/US 00/01596

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B17/00 A61F2/00 A61F2/02

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages  | Relevant to claim No. |
|------------|---|-----------------------|
| Y          | US 5 192 314 A (DASKALAKIS)<br>9 March 1993 (1993-03-09)<br>column 6, line 4 - line 27; figure 1                          | 1,5,6                 |
| Y          | US 5 741 298 A (MACLEOD)<br>21 April 1998 (1998-04-21)<br>column 7, line 60 - line 67; figure 1                           | 1,5,6                 |
| P,X        | WO 99 56655 A (CORRESTORE, INC.)<br>11 November 1999 (1999-11-11)<br>page 15, line 11 -page 17, line 7; figures<br>12A-20 | 1-6                   |
| A          | WO 93 13712 A (REGENTS OF THE UNIVERSITY<br>OF MINNESOTA) 22 July 1993 (1993-07-22)<br>abstract; figure 5A                | 1,5,6                 |
|            | -/--  |                       |



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

## \* Special categories of cited documents:

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"8" document member of the same patent family

Date of the actual completion of the international search

17 May 2000

Date of mailing of the international search report

30/05/2000

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Ducreau, F



# INTERNATIONAL SEARCH REPORT

Int. Application No

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## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages                     | Relevant to claim No. |
|------------|--|-----------------------|
| A          | <p>WO 91 19465 A (FRATER)</p> <p>26 December 1991 (1991-12-26)</p> <p>page 10, paragraph 2 -page 1</p> | 1,5,6                 |

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 00/01596

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 00/01596

| Patent document<br>cited in search report | Publication<br>date | Patent family<br>member(s) | Publication<br>date |
|---|---------------------|----------------------------|---------------------|
| US 5192314 A                              | 09-03-1993          | NONE                       |                     |
| US 5741298 A                              | 21-04-1998          | US 5947922 A               | 07-09-1999          |
| WO 9956655 A                              | 11-11-1999          | US 6024096 A               | 15-02-2000          |
|   |                     | AU 2570599 A               | 23-11-1999          |
| WO 9313712 A                              | 22-07-1993          | CA 2128338 A               | 22-07-1993          |
|   |                     | DE 69324239 D              | 06-05-1999          |
|   |                     | DE 69324239 T              | 04-11-1999          |
|   |                     | EP 0623003 A               | 09-11-1994          |
|   |                     | EP 0876793 A               | 11-11-1998          |
|   |                     | ES 2133382 T               | 16-09-1999          |
|   |                     | JP 7502918 T               | 30-03-1995          |
|   |                     | US 5334217 A               | 02-08-1994          |
|   |                     | US 5578045 A               | 26-11-1996          |
| WO 9119465 A                              | 26-12-1991          | AU 8188191 A               | 07-01-1992          |
|   |                     | BR 9106527 A               | 25-05-1993          |
|   |                     | CA 2084517 A               | 08-12-1991          |
|   |                     | DE 69119415 D              | 13-06-1996          |
|   |                     | DE 69119415 T              | 19-09-1996          |
|   |                     | EP 0532678 A               | 24-03-1993          |
|   |                     | ES 2085998 T               | 16-06-1996          |
|   |                     | JP 5509013 T               | 16-12-1993          |
|   |                     | PL 166863 B                | 30-06-1995          |
|   |                     | RO 108918 A                | 31-10-1994          |
|   |                     | US 5415667 A               | 16-05-1995          |